Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rochville
MD 20852
United States of America

Scantox

11 April 2003

Docket Numbers: 03D-0060, **99D-1458**, 00D-1538, 00D-1543, 00D-1542, 00D-1539

Dear Sir/Madam

Comments on the draft Guidance for Industry

Part 11, Electronic Records; Electronic Signatures – Scope and Application

Section III, B, 1; Narrow Interpretation of Scope.

Line 143-144 states: We understand that there have been different views expressed about the scope of Part 11. Some have understood the scope of Part 11 to be very broad.

→ The interpretations of the term "metadata" as increased during the last years have significantly broadened the scope of Part 11. Clarification on the expected FDA attitude to metadata would be appreciated. Example: Laboratory equipment printing data immediately as the results are available. Data are not saved within the system, data cannot by any end user be accessed or changed and the print outs are relied upon to perform regulated activities. However, several configurable metadata are saved within the system, defining how the equipment will run the analysis in question. Would such a system fall within the scope of Part 11?

Line 151-154 states: On the other hand, when persons use computers to generate paper printouts of electronic records, those paper records meet all the requirements of the applicable predicate rules, and persons rely on the paper records to perform their regulated activities, the *merely incidental* use of computers in those instances would not trigger Part 11.

→ What would be the expected FDA attitude to paper records, meeting all the requirements of the applicable predicate rules, relied upon to perform regulated activities, yet the content of such paper record print outs are dependent on an automated process? Clarification on whether or not such a situation would trigger Part 11 would be appreciated.

00D-1539 C 30

Scantox A/S
Hestehavevej 36A, Ejby
DK-4623 Lille Skensved
Denmark

Tel +45 56 86 15 00
Fax +45 56 82 12 02
E-mail info@scantox.com
www.scantox.com

DANAK Reg No 145

VAT No 83090413
A.S Reg No 65808

Bank Amagerbanken
DKK Account No 5190 200871 6
EUR Account No 5201 967263 8
SWIFT AMBKDKKK

Section III, C, 2; Audit Trail

→ With regards to the new approach to audit trail, does the phrases "audit trails or other physical, logical or procedural security measures" (line 225-226) and "audit trails, or other appropriate measures" (line 227-228) implies that procedural controls like procedure enforcement and/or documented QC checks be an acceptable alternative to a computer-generated, time-stamped audit trail.

FDA elaboration on these topics would be greatly appreciated.

IT compliance working group
SCANTOX